STUDY INFORMED CONSENT

Addressing the Opioid Epidemic Through Community Pharmacy Engagement: Randomized Controlled Trial (Aim 2)

NCT number NCT04677387
Document Date 10/10/2022

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: October 10, 2022
IRB Study # 20-2192
Title of Study: Addressing the Opioid Epidemic through Community Pharmacy Engagement: Randomized Controlled Trial
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Funding Source and/or Sponsor: NIH National Institute on Drug Abuse (NIDA)

CONCISE SUMMARY

The purpose of this research study is to evaluate the usefulness of naloxone education materials for pharmacists. Continuing education (CE) credit will be provided for completion of the training which will last approximately 30-60 minutes. You will also receive up to $150 in Amazon eGift cards for participating in this study. Your participation in the naloxone training is completely voluntary and you can choose to discontinue participation at any time. As part of the evaluation, you will be asked to complete brief surveys before and after completing the training. At various times, individuals will observe your naloxone communication and provide feedback on your interaction with them at the end of the study. Survey responses and observations will not be shared with your employer, results will be reported in aggregate, and will not affect employment. At the conclusion of the study, we will request your pharmacy's naloxone prescribing data for the 3 months pre- and post-training in order to assess changes in amount of naloxone prescribed.

We do not anticipate major risks during the study; however, the greatest risks of this study include breach of confidentiality.

If you are interested in learning more about the study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. You do not have to be in this study if you don't want to. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher or the University of North Carolina-Chapel Hill.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any

time.

What is the purpose of this study?
The purpose of this research study is to evaluate the usefulness of naloxone education materials for pharmacists. You are being asked to be in the study because you are a practicing pharmacist who works at a rural community pharmacy that stocks naloxone.

Are there any reasons you should not be in this study?
You should not be in this study if you: 1) do not work full-time as a pharmacist at a rural community pharmacy, 2) are not at least 18 years of age, 3) do not speak English, 4) are a floater, and/or 5) your pharmacy does not stock naloxone.

How many people will take part in this study?
If you decide to be in this study, you will be one of 60 rural pharmacists in this research study.

How long will your part in this study last?
Your part in this study will last approximately 2 hours, which includes the baseline survey, communication observations, naloxone training (~30-60 minutes), and post-training evaluation/surveys. After completing the final 3-month follow-up survey, your participation in our research study will be over.

What will happen if you take part in the study?
You will first complete a baseline survey that asks questions about your demographics, pharmacy characteristics, and naloxone knowledge and attitudes. You will be assigned to one of two possible naloxone trainings. You will be emailed a link and asked to complete the naloxone training. Immediately after completing the training, you will complete an evaluation to receive CE credit. Your name, email address, NABP number, and date of birth (MMDD only) are required to process CE credit. You must complete and submit a program evaluation in order to receive CE credit. If you do not provide your email address, NABP number, and date of birth (MMDD only), or complete the evaluation noted above, we cannot issue you CE credit for this training. However, you may still choose to participate in this study.

Your communication behaviors will be observed by study personnel sometime over a 6-month period, but these observations will not be shared with your employer, results will be reported in aggregate, and will not affect your employment. Three months after the training, you will be asked to complete a final follow-up survey. For all surveys, you have the right to refuse to answer any question that makes you feel uncomfortable or discontinue participation at any time.

At the conclusion of the study, we will contact you or your pharmacy's owner/manager to ask for your pharmacy's naloxone prescribing data for the 7 month study period. Specifically, we will be asking for the rate of naloxone prescriptions per opioid prescriptions. We will not be asking for individual records, but rather aggregated rates for the 3 months pre-training, the month during which training occurred, and the 3 months post-training.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. Continuing education (CE) credit will be provided for completion of the training.

What are the possible risks or discomforts involved from being in this study?
We do not anticipate major risks during the study; however, the greatest risks of this study include breach of confidentiality. Confidentiality will be breached in the case that you need medical assistance or counseling. In this case, you will be referred to Dr. Evon (Co-Investigator) who will make additional appropriate referrals as necessary. Survey responses and observations will not be shared with your employer, results will be reported in aggregate, and will not affect employment. Although the communication observations may cause the pharmacist to feel uncomfortable or distressed, the scenarios will be realistic and not outside the range of what pharmacists would be asked to navigate as part of their

normal professional duties. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

How will information about you be protected?
Communication observations will occur in the public pharmacy setting, but procedures will be undertaken to ensure confidentiality. Your name and/or other potentially identifying information will be collected strictly for the purpose of contact and/or coordination of continuing education credit. Any identifying information collected will be removed from data sets and you will be assigned an identification number. A list which links your name to identification numbers will be kept in a password-protected file on a secure UNC server. All other data will be stored in a secured fashion with password-protected files, secure servers, or locked filing cabinets, as appropriate. Only Dr. Carpenter and the research staff will have access to the list that links names to identification numbers as well as all other data. Data will not be shared with your employer.

Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

In addition, this study has been issued a Certificate of Confidentiality.

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
In addition to CE credit, you will receive up to $150 for participating in the study, including $50 for enrolling and completing the baseline survey, $50 for completing the online module and post-training

survey, and $50 for completing the final 3-month follow-up survey. Any payment provided for participation in this study may be subject to applicable tax withholding obligations.

Will it cost you anything to be in this study?
There will be no costs for being in the study.

Who is sponsoring this study?
This research is funded by the NIH National Institute on Drug Abuse (NIDA). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

- ○ Yes. I wish to participate.
- ○ No. I do not wish to participate.